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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,662	12/17/2001	Hideshi Fujiwake	011658	5139

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ARMSTRONG, WESTERMAN & HATTORI, LLP  
1725 K STREET, NW  
SUITE 1000  
WASHINGTON, DC 20006

EXAMINER

DAVIS, DEBORAH A

ART UNIT PAPER NUMBER

1641

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

10/015,662

Applicant(s)

FUJIWAKE, HIDESHI

Examiner

Deborah A Davis

Art Unit

1641

-- The MAILING DATE of this communication appears n the c ver sheet with the corresp ndence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. Applicants' response to the Office Action mailed March 13, 2003 in Paper #3 is acknowledged. Currently, claims 1-6 are under consideration. Claims 3, 5-6 has been amended for correction.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coull et al (USP#5,011,861) in view of Rose et al (Manual of Clinical Laboratory Immunology, Fourth Edition).

Coull et al teaches a method for determining an amino acid or protein sequence and immobilizing them to a solid phase membrane. Coull et al describes that sequences of a protein or peptide can be deciphered by a stepwise chemical or enzymatic degradation from either the amino-(N-) or carboxyl-(C-) terminal end. Single amino acids are removed one by one from the polypeptide chain, separated and identified. This procedure is carried by the Edman degradation method which describes removing one amino acid residue from its amino-terminus with an isothiocyanate (ITC) in a solvent under basic or anhydrous conditions to form various

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side products, such as phenylthiocarbamate (PTC), anilinothiazolinone (ATZ) and phenylthiohydantoins (PTH) derivatives (columns 1 and 2).

Coull et al does not teach the use of a competitive assay to determine the liberated constitutive amino acid.

However, Rose et al teaches the advantages of using a competitive assay that can use either antibodies or antigens on a solid phase. When the assay design used a specific antibody (monoclonal) coated on a solid phase, the antigen in question and the labeled antigen are added simultaneously and compete for binding. As with any competitive assay technique the antigen is incubated with the antibody to form a complex that are removed during wash steps. A labeled antigen is then added to react with any remaining antibody not bound to the first antigen. Competitive assays offer great specificity and are ideal for measuring relatively small molecules that can be obtained in relative purity and in large enough amounts to be labeled. Competitive assays only require small amounts of antibody and are ideal for use in systems that have a limited amount (fixed) of antibody available (Chapter 2, pages 2 and 3).

It would have been obvious to one of ordinary skill in the art to utilize a competitive assay to determine liberated constitutive amino acids as disclosed by Rose et al in the method of Coull et al because competitive assays offer great specificity and are ideal for measuring small molecules that can be obtained in large enough amounts to be labeled.

***Response to Arguments***

4. Applicant's arguments filed June 11, 2003 have been fully considered but they are not persuasive:
5. Applicants' argument that there is no suggestion in Coull et al to analyze the amino acids released in the Edman degradation by any method other than HPLC with UV/Vis detection and there is not motivation in Coull et al to use another detection method, is not found persuasive. Coull et al is the primary reference that describes the removal of amino acids by the Edman degradation method. The amino acids were not only analyzed by HPLC but with binding assays (column 22, lines 25-37).
6. Applicants' argument that there is no suggestion in Rose et al to use enzyme-linked immunoassays to analyze amino acids from Coull et al Edman degradation or from amino acid analysis is not found persuasive because the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Coull et al teaches analyzing amino acids from the Edman Degradation method and teaches a binding assay method to determine the amino acids groups. Coull et al does not teach a competitive binding assay, but one advantage of utilizing a competitive format would be its sensitivity in that it offers greater specificity

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and are ideal for measuring relatively small molecules (See Rose et al, Chapter 2, pages 2-3). There for the Examiner relies on Rose et al to teach the advantages of using a competitive assay method for analyzing small molecules which can include amino acids among others.

7. Applicants' argument that Rose et al and Coull et al may not even be enabling for present claim 1 because there is not disclosure in Coull et al regarding detection of derivitized amino acids by enzyme-linked immunoassay is not found persuasive because as noted above, both Rose et al and Coull teach binding assays for detection purposes. Competitive binding assays such as enzyme-linked or other competitive binding assays are well known in the art for it sensitivity in detecting small samples. Therefore, the Examiner only relies on the reference of Rose et al for teaching advantages of why one of ordinary skill in the art would want to use a competitive binding assay, as disclosed in claim 6 of applicants' instant invention.

8. In addition, Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

### ***Conclusion***

9. No claims are allowed.

**10. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

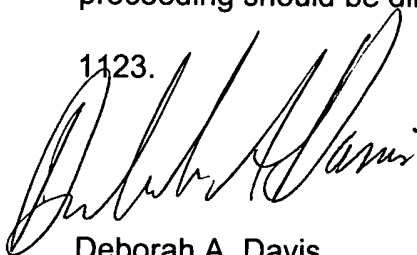
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

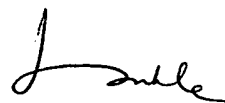
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1123.



Deborah A. Davis  
CM1, 7D19  
August 21, 2003



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

08/22/03